

	Search Text
1	600/585.ccls.
2	128/899.ccls.
3	600/585.ccls. or 128/899.ccls.
4	magnetic
5	(600/585.ccls. or 128/899.ccls.) and magnetic
6	sinus
7	((600/585.ccls. or 128/899.ccls.) and magnetic) and sinus
8	"3043309".PN.
9	"3358676".PN.
10	"3769984".PN.
11	"4063561".PN.
12	"4244362".PN.
13	"4809713".PN.
14	"4944727".PN.
15	("3674014").PN.
16	"5055101".PN.
17	"5090956".PN.
18	"5129404".PN.
19	"5257636".PN.
20	"5353807".PN.
21	"5431640".PN.
22	"5449369".PN.
23	magnetic
24	magnet
25	magnetic or magnet

	Search Text
26	distal
27	(magnetic or magnet) with distal
28	128/899.ccls.
29	((magnetic or magnet) with distal) and 128/899.ccls.
30	607/\$.ccls.
31	600/585.ccls.
32	((magnetic or magnet) with distal) and 607/\$.ccls.) and 600/585.ccls.
33	((magnetic or magnet) with distal) and 607/\$.ccls.
34	guidewire
35	(magnetic or magnet) and guidewire
36	pacing
37	((magnetic or magnet) and guidewire) and pacing
38	vasculature
39	(magnetic or magnet) same vasculature
40	catheter
41	((magnetic or magnet) same vasculature) and catheter
42	distal and ((magnetic or magnet) same vasculature) and catheter)
43	((("4244362") or ("5931818"))).PN.
44	stylet
45	catheter
46	guidewire
47	stylet and catheter and guidewire
48	607/122.ccls.
49	(stylet and catheter and guidewire) and 607/122.ccls.
50	(600/528).CCLS.

	Search Text
51	magnet\$5
52	((600/528).CCLS.) and magnet\$5
53	604/528.ccls.
54	magnet\$5 and 604/528.ccls.
55	("3674014").PN.

United States Patent

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[54] MAGNETICALLY GUIDABLE CATHETER-TIP AND METHOD

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138/120, 138/155, 335/306

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[58] Field of Search128/2 M, 2.05 R, 4.6-8,
128/303 R, 348, 349 R, 350 R, 1.3, 1.4, 356;
138/120, 155; 355/302, 306

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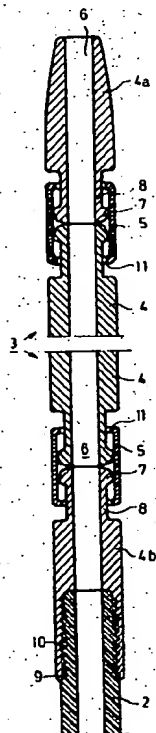
Attorney—Brumbaugh, Graves, Donohue & Raymond

[57]

ABSTRACT

A flexible catheter-tip, guidable by a magnetic field into selected arteries of the body, includes a plurality of permanent magnetic tubular sections with ball-shaped ends arranged end-to-end. Each pair of adjacent ends is encased within a tubular link formed of non-magnetic material which provides a flexible, fluid-tight seal between the tubular sections. Each ball-shaped end has formed thereon a bevel to provide stability between adjacent sections, and therefore to the whole catheter-tip, at full bend.

8 Claims, 4 Drawing Figures



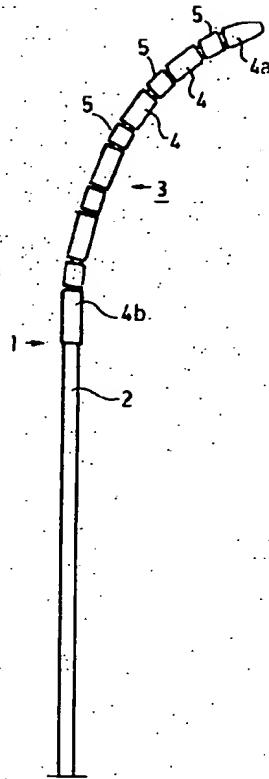


Fig. 1

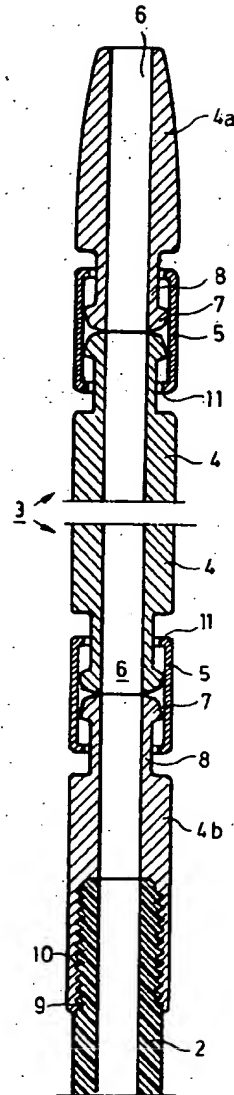


Fig. 2

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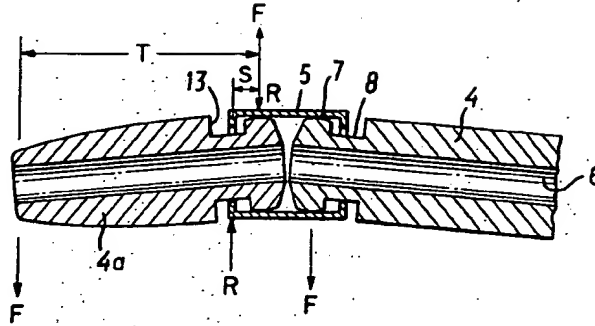


Fig. 3

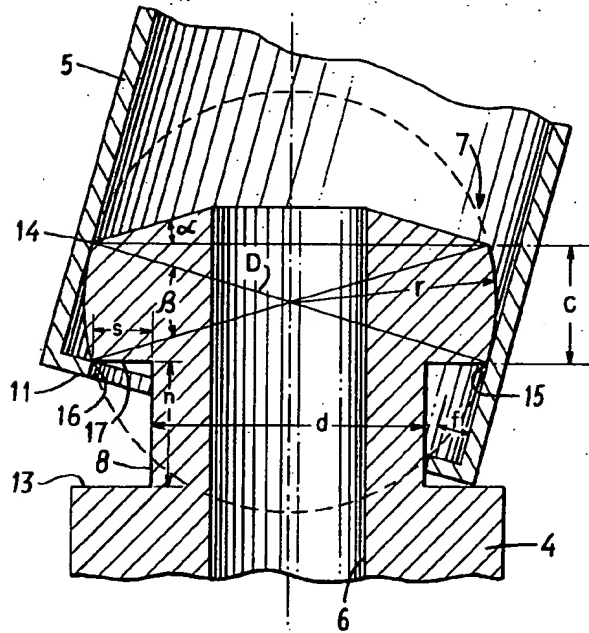


Fig. 4

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MAGNETICALLY GUIDABLE CATHETER-TIP AND METHOD

BACKGROUND OF THE INVENTION

This invention relates to magnetically guidable catheter-tips and, more particularly, to a catheter-tip for insertion into the vascular system of a body and guided therethrough by an external magnetic field to selected vessels or organs.

Recently developed medical procedures require the placement of a catheter or fine tube into selected vessels or organs within the body. For example, in the practice of arteriography of the distal vessels it is necessary to inject a roentgenographic substance into the selected area before taking the X-ray. In addition, certain therapeutic techniques require the injection of certain medicines by way of the vascular system directly into the selected organ.

The placement of the catheter into the selected region of the body is accomplished usually by opening an artery in the thigh and inserting the catheter into the artery whence it is fed up through the artery system to the aorta. No external guidance is required to this point since the arteries divide away from the heart and the catheter will be following a path of converging arteries. To reverse the direction and feed the catheter into the smaller arteries branching from the aorta, external guidance is required to direct the catheter into the desired branch.

Previously, a number of different methods have been suggested for guiding the catheter to the selected artery. One of the earlier techniques was the so-called pre-bent tip. The tip of the catheter was biased in a bent configuration, but was held straight by a removable means such as a guiding thread. When the catheter reached the desired branch of the vessel, as observed on an X-ray machine, the guiding thread extending inside the catheter was extracted and the catheter-tip would bend into the vessel. This procedure was extremely difficult because the tip would bend only in one plane and it was necessary to orient the catheter-tip so that the direction of bending would coincide with the direction of the branch of the artery. Moreover, the bending could be accomplished only once and thereafter the catheter-tip would remain bent. This device is useful for reaching arteries close to the heart, but not for reaching the distal vessels.

Another technique uses guiding threads which extend from the catheter-tip along the bore of the catheter and out the end. By pulling in selected guiding threads the catheter-tip could be bent in any desired direction. While this technique appears to eliminate the single plane bending restriction of the first catheter-tip, it is still extremely difficult, if not impossible, to bend the catheter-tip in a new direction once having been bent from the straight configuration. Moreover, it is an awkward and difficult device to operate with any precision, especially when the catheter follows a long and/or tortuous path through the vascular system.

The inventor has previously described an externally guidable catheter-tip which includes a number of cylindrical tubular sections, arranged to each other by means of ball-joints, each of the sections having a ball at one end and a casing at the other. The sections, which are identically alike, are made of non-corroding stainless steel having magnetic properties, that is, capable of being attracted by a magnet. The catheter-tip is attracted by a magnetic field generated by equipment outside the body and swings in that direction, thereby enabling the operator to cause the tip to swing in any desired direction with no limit to the number of turns the tip may make. This technique constitutes a great improvement over the prior art, but itself requires refinement. This catheter-tip will bend only in an arc with a large radius of curvature and high intensity magnetic field strengths are required to effect even this much bending. These high intensity magnetic field strengths require large, heavy, and expensive magnetic equipment for their generation and control, and they interfere with the X-ray observation system.

Thus, a need has arisen in the art for a catheter-tip guidable with great precision from the exterior of the body using low-intensity magnetic fields to preclude interference with the X-ray observation system.

SUMMARY OF THE INVENTION

Accordingly, one object of this invention is to provide a catheter-tip precisely guidable through the vascular system of a body from the exterior of the body.

Another object of this invention is to provide an externally guidable catheter-tip which is precisely guided by small and low-cost support equipment.

Another object of this invention is to provide a catheter-tip which may be guided through the body's vascular system without interference with the observation equipment.

A further object of the invention is to provide a small diameter catheter-tip bendable under the influence of a weak magnetic field in an arc of small radius of curvature.

A still further object of this invention is to provide an externally guidable catheter-tip which may be repeatedly bent and straightened by means of an externally generated, relatively weak magnetic field and is of sufficiently fine diameter that it can be directed into the distal vessels.

These and other objects of the present invention are attained by providing a catheter-tip having a plurality of short permanent magnets disposed with their magnetic axes parallel and co-directional and joined together to form a flexible fluid-tight conduit which will experience a strong moment in the presence of a magnetic field.

IN THE DRAWINGS

A more complete appreciation of the invention and its many attendant advantages will develop as the same becomes better understood by reference to the following detailed description when read in connection with the accompanying drawings wherein:

FIG. 1 is an enlarged view of the flexible catheter-tip connected to a catheter;

FIG. 2 is a greatly enlarged sectional view of the front section and the rear section of the catheter-tip with the central portion removed;

FIG. 3 is a sectional view similar to FIG. 2 but showing a single connection between two tubular sections at partial bend; and

FIG. 4 shows an even more greatly enlarged view of a single end of a tubular section at full bend.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring now to the drawings wherein like reference characters designate similar or identical parts and, more particularly, to FIG. 1, a catheter 1 is shown having a catheter-tube 2 to which is connected the flexible catheter-tip 3 of the present invention. Tip 3 is a tube formed of a plurality of individual cylindrical tubular sections 4 connected end-to-end by cylindrical connecting links 5. The lengths of sections 4 decrease toward the tip end so that each section is shorter than its rearwardly adjacent neighbor.

Looking now at FIG. 2, an axial bore 6 extends completely through each section 4 communicating between both ends, each of which is formed as a ball connector 7 integrally joined to its tubular section 4 by means of a reduced diameter neck portion 8. The outer end of the outermost link 4a is conically tapered towards its front end and provided with rounded edges to facilitate the introduction into a vessel. The rear section 4b is intended to be screwed onto the tapered end of a thermoplastic catheter-tube and for this purpose is provided at its rear end with an enlarged bore 9 internally threaded at 10. The threads 10 will cut matching threads into the thermoplastic material of catheter 2 thereby forming a strong and reliable connection between the catheter-tip and the catheter and, as shown in FIG. 2, providing an almost stepless connection between the tip 3 and the tube 2. The inner ends of sec-

tions 4a and 4b are provided with ball connections 7 identical to the ends of the central sections 4.

Tubular sections 4 are made of a permanent magnetic material that is inert to blood. One alloy found to give excellent results is a material sold under the trademark Platinax II which consists of 98% by weight of cobalt and 2 percent by weight of platinum. The sections are permanently magnetized and arranged end-to-end with adjacent ends of opposite polarity so that the magnetic vectors at each section are aligned and co-directional. The sections are therefore mutually attractive to yield the combined advantages of an improved fluid seal between the sections and a self-straightening feature.

To bend the tip into a selected artery, a magnetic field is applied in the direction the tip is to bend. Each section, flexibly connected to its neighbor by a connecting link to be described below, experiences a pure moment which tends to rotate the section to align its own magnetic field, and its axis, with the externally applied magnetic field. The plurality of individual moments experienced by the plurality of magnetic sections combine to bend the tip in a tight arc. The pure moment experienced by each section 4 is contrasted with the mechanism by which the prior art flexible catheter-tip is bent. That bending occurs by mere gross attraction of the metal tip which causes the free tip end to swing in the direction of the magnetic field while the other end is restrained by reason of its attachment to the catheter tube. The "pure moment" experienced by the section 4 of this invention occurs by reason of the oppositely directed forces acting on the poles of opposite polarity.

The flexible connection between adjacent sections will now be described with reference to FIGS. 3 and 4. The link 5 is made of a non-magnetic stainless steel to minimize the gross attraction of the tip in a magnetic field, and is formed as a short length of cylindrical tubing having each end turned radially inward to form a full circumferential flange 11 at each end. The interior diameter of link 5 is substantially identical to the exterior diameter of ball-end 7 of each tubular section 4. A reliable fluid connection is thereby achieved between the adjacent tubular sections 4 by means of the constant close-fitting contact between connecting link 5 and ball-end 7 regardless of the angular orientation of tubular section 4. It will be noted that connecting link 5 can be made substantially longer than the combined axial length of the two ball-ends 7 illustrated in FIG. 3. This greater length of connecting link 5 is for the purpose of providing maximum strength and minimum diameter of the flexible catheter-tip 3, as will appear from the following discussion. Consider a single tubular section 4a subjected to the influence of a magnetic field, externally applied, for the purpose of bending the catheter-tip 3. The section 4a, which is a magnetic dipole, will tend to rotate in the magnetic field to align its own magnetic field with that of the externally applied one. The moment that is exerted on section 4a can be considered a pair of equal, but oppositely directed, forces respectively exerted on the respective ends of the section and is equal to the product FT, where F is the force exerted on each end and T is the length of the section. At the designed maximum angular bend of the catheter-tip, this moment must be resisted by a counteracting moment exerted by the catheter-tip itself. This counteracting moment is supplied by connecting links 5 in the form of a pair of reaction forces R, one of which is exerted transversely on the ball-end 7 and the other of which is exerted by the flange 11 of link 5 on the neck 8. The moment arm between these forces is the short distance S. Thus, the counteracting moment is equal to RS, which must be equal to the moment FT. The reason for the extended length of link 5 now becomes apparent: if the link 5 were shorter, the moment arm S would be shorter. To hold the counter-acting moment RS equal to moment FT it would then be necessary to increase the magnitude of reaction force R. To exert the greater force R, the connecting link 5 would have to be stronger and therefore thicker. The resulting thick link 5 would result in a catheter-tip thicker than is achieved with the

present invention and of less utility in the narrow distal vessels wherein the present invention finds particular utility.

Referring now to FIG. 4, connecting link 5 is held centered on the junction between tubular sections 4 by choosing the length of neck 8 so that, at the designed maximum bend of the catheter-tip, the shoulder 13 formed at the junction of the neck 8 and the main tubular body of each section 4 abuts against the flange 11 of link 5.

The ball-end 7 is bevelled on its outer end to form a blunt conical end, having a base angle α of from 10° to 12° . The purpose of the bevel at the end is, first, to shorten the ball-end by removing portions of the ball not needed to effect the seal with connecting link 5. This enables the ball-end to extend farther into connecting link 5, thereby extending the moment arm S by that amount. The base angle α is selected to coincide with the angle of the designed maximum bend between the section axis and the link axis. Thus, at maximum angular displacement, the outside face of ball-end 7 will, along one chord, be perpendicular to the axis of tubular link 5. Since the facing ball-end 7 of the adjacent tubular section 4 is identically bevelled, the facing surfaces of the two ball-ends will, along one chord, be in full tangential line contact. Tangential line contact between ball-ends 7 contributes significant stability to the flexible catheter-tip at its configuration of maximum angular deflection. It will be noted that the angle β subtended by the arc of radius r constituting the spherical portion of the ball-end is approximately 20° to 24° . This coincides with the full angular swing which the section will experience from one to the opposite maximum deflection. It also coincides with the angle between two adjacent sections at full bend. It may be advisable to increase angle β a few degrees to provide assurance of fluid integrity since some tolerance must be designed into the dimensional parameters of the link 5 and ball-end 7.

The optimum dimensional parameters of the ball connector 7 and flange 11 to achieve maximum angular displacement with minimum ball thickness, while assuring a secure fluid seal, are given by the following conditions: the base angle α of the ball-end bevel equals the maximum angular deflection of the tubular section from the axis of link 5; the diameter D extending from the outside corner 14 of the ball to the inside corner 15 is, at full bend, perpendicular to the link axis; the radial dimension of the flange is such that at full bend one side of the flange touches the neck portion 8 and the diametrically opposite side touches the inside corner 16 of the ball 7 diametrically opposite the inside corner 15; and the length n of neck 8 is such that shoulder 13 abuts against the outside circumferential edge of link 5 at full bend. Given these conditions, selection of r and α determines the magnitude of the dimensional parameters c , d , f , n and s , where c is the length of the chord of the arc subtending angle β , d is the diameter of neck 8, and f and s are the radial lengths of flange f and shoulder 17 respectively. The relationships which may readily be determined by elementary trigonometry, are as follows:

$$\begin{aligned} c &= 2r \sin \alpha & s &= 2f = 4r \sin^2 \alpha \\ d &= 2r (\cos \alpha - 8 \sin^2 \alpha) & n &= 2r \sin \alpha \cos^2 \alpha \end{aligned}$$

This arrangement theoretically, produces the shortest links, the thinnest ball-ends and the maximum stability and strength for the flexible tip for a given ball radius and angle α . In actual physical embodiments, however, it is necessary to account for the tolerance that must be built into every manufactured article, as is well known to those skilled in the art.

The dimensions of the above-described illustrative embodiment of the invention are as follows: the outside diameter of sections 4 is about 2.1 mm and their lengths vary from about 6 mm for section 4b to about 3 mm for section 4a. The inside diameter of the bore 6 is about 0.6 mm.

The connecting links 5 are all identical, having a diameter of about 2.1 mm and a length of about 2.2 mm. The links and sections may be connected by introducing ball-end 7 into the cylindrical link and then rolling the ends of the links to form the inwardly turned flange 11.

Naturally, other configurations are possible and expressly contemplated by this invention. In particular, as noted previously, the greater the length of link 5, the stronger a resisting moment may be applied for a given thickness of link material, and the shorter the flange 11 and the longer the chord c, the greater is the maximum possible turning angle. With the foregoing description, it should be within the competence of one skilled in the art to modify the dimensions of the length and thickness of the link and its flange, and the parameters of the ball-end 7 and neck 8 to achieve whatever design specifications are desired. Moreover, it is possible to design the arc described by the tip by varying the lengths of sections 4. Thus a circular arc can be achieved by making all sections 4 of equal length; a parabolic or hyperbolic arc is achieved by selectively decreasing the length of sections 4 toward the tip end.

Certain alternative connecting means are contemplated for use in place of the cylindrical stainless steel link 5. For example, it is contemplated that a short length of flexible plastic-tubing may be connected between adjacent tubular sections 4 as by heat shrinking or other technique.

Another embodiment contemplated substitutes for the magnetic tubular sections and non-magnetic connecting links, a flexible tube of non-magnetic material such as plastic, and embedded in the walls of the tube a multiplicity of small magnetic dipoles arranged with their axes parallel to the tube axis and co-directional, that is, with like poles all facing the same direction. This arrangement will permit somewhat greater design flexibility since the shape and number of the small magnetic magnets can be varied within wide ranges. For example, it may be desired to use a small number of thick magnets, slightly narrower than the thickness of the tube wall, or a multiplicity of fine magnetized wires thinner than a hair. It is thus possible to select the design for optimum manufacturing ease and, at the same time, achieve whatever turning radius and catheter diameter may be desired. It is, therefore, to be understood that the invention may be practiced otherwise than specifically described in the foregoing illustrative example while remaining within the scope of the invention which is claimed as follows.

I claim:

1. A flexible catheter tip, comprising tubular means having means therethrough defining an axial bore, said tubular means including:

a plurality of individual permanent magnetic dipoles disposed along said tubular means with their magnetic axes codirectional and parallel to said axial bore; and means forming a flexible fluid-tight connection between said magnetic dipoles; whereby said tubular means may be bent in a curve having a direction and radius of curvature which is controllable by a controllable magnetic field.

2. The flexible catheter-tip defined in claim 1, wherein: said individual magnetic dipoles comprise tubular sections having ball-shaped ends;

said connection means comprises cylindrical tubular links formed of non-magnetic material encasing adjacent ball-shaped ends and having substantially the same interior diameter as the exterior diameter of the ball-shaped ends encased thereby; and

said connection means and said tubular sections together

constituting said tubular means.

3. The flexible catheter-tip defined in claim 2, wherein: said ball-shaped ends are bevelled on the outer ends thereof to form blunt conical ends;

said bevel has a base angle with respect to the axis of its section substantially the same as the maximum designed angular deflection of said section from the axis of the link in which said ball-end is encased.

4. A flexible catheter-tip having a front end and rear end, comprising:

a plurality of permanent magnets disposed with their respective magnetic axes mutually co-directional; means through said magnets defining an axial bore communicating between said front end and said rear end; and flexible connecting means for forming a flexible fluid-tight connection between said magnets whereby said axial bore forms a fluid-tight conduit from one end of said tip to the other.

5. A flexible catheter-tip, comprising:

a plurality of tubular sections formed of permanent magnetic material and magnetized such that one axial end thereof is a south magnetic pole and the other axial end is a north magnetic pole;

said sections arranged axially end-to-end with adjacent ends of opposite magnetic polarity;

means forming an axial bore through each section; and means for flexibly connecting the adjacent ends of said sections together and for establishing fluid-tight communication between said balls.

6. The flexible catheter-tip defined in claim 5, wherein said connecting means comprises:

a ball-shaped connector formed on the ends of said sections; a cylindrical tubular link surrounding each pair of adjacent ball connectors on adjacent sections;

the interior diameter of said link and the exterior diameter of said connector being substantially identical;

the outer end of said connector being formed with a blunt conical face; and

the base angle of said conical face being substantially identical to the maximum angular deflection of said section from the axis of said link whereby tangential line contact is established between abutting conical faces of adjacent connectors at maximum bend of said tip.

7. The flexible catheter-tip defined in claim 6, further comprising:

an inwardly directed radial flange formed on each end of each link;

a reduced diameter neck portion joining said ball connector to said section and defining, at its junction with said connector, a shoulder;

said flange having a radial extent sufficient to engage said shoulder regardless of the angular orientation of said section with respect to said link.

8. The flexible catheter-tip defined in claim 7, wherein:

each neck and its respective section form at their junction a second shoulder; and

said neck having an axial extent such that, at full angular deflection of said section with respect to said link, said flange engages both of said first and said second shoulders.

* * * * *